



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,910	11/28/2000	Hugh J. Pasika	7414.0025	8658

22852 7590 08/09/2005

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

WHALEY, PABLO S

ART UNIT PAPER NUMBER

1631

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,910	PASIKA ET AL.	
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7-13,16-24,26,27 and 29-45 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,4,5,7-13,16-24,26,27 and 29-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,2,4,5,7-13,16-24,26,27 and 29-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

S-d'6

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments, filed 6/17/2005, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 34-45. Claims 35, 39, and 43 have been amended. Claims 3, 6, 14, 15, 25, and 28 have been cancelled. This application contains claim 1, 2, 4, 5, 7-13, 16-24, 26, 27, and 29-33 drawn to an invention non-elected without traverse in the 'Restriction/Election Requirement' mailed 15 January 2002. Applicants are suggested to cancel these claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for

Art Unit: 1631

patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following prior art publications are the basis for executing this rejection:

I. Claims 34, 38, and 42 are rejected under the first paragraph of 35 USC § 102(b) as being anticipated by Palsson et al (*Using Quality Measure to Facilitate Allele Calling in High-Throughput Genotyping*, Genome Research, Vol. 9, p. 1002-1012, October 1999). This rejection is maintained and reiterated from the previous office action, mailed Dec. 17, 2004.

Applicant argues that Palsson fails to perform any threshold test to analyze data before determining if an allele call should be made. The applicant's arguments are not deemed to be persuasive.

As stated in the previous office action, mailed Dec. 17, 2004, Palsson teaches an allele-calling program combined with quality measures and empirically derived criteria (i.e. peak height and shift) for accurate genotyping and minimization of ambiguous allele calls. Using nucleic acid information, Palsson applies a commercially available allele-calling program (TrueAllele) that use quantitation and deconvolution algorithms to make allele calls. The input signal (nucleic acid information) receives a numerical quality threshold score based on peak height, shape, and PCR stutter pattern. Palsson then applies a computer program (Decode-GT), which analyzes the data (allele calls) and sorts the data into three categories (bad allele calls, good allele calls, and ambiguous allele calls). Sorting is based on a threshold test that is established by

TrueAllele quality measures, peak heights, and peak shifts (i.e. analyzing procedure, page 1003, right column, lines 45-55). Thus Palsson anticipates the instantly claimed invention because it teaches a method for making an allele call (TrueAllele) and a method for analyzing a signal to determine if an allele caller made a correct call (Decode GT) that is based on thresholding.

In Claims 34, 38, and 42, the applicant discloses: (1) receiving the signal representing nucleic acid information; (2) analyzing the signal to determine if the signal meets a threshold test of an allele caller making a correct call; (3) making a allele call for the signal if the threshold test is met. Applying the method described in Step 3 before Step 2 as disclosed in Claims 34, 38, and 42 results in the same method as described by Palsson, and thus the instantly claimed invention is not patentably distinguished from Palsson. The applicant teaches several exemplary algorithms for making appropriate calls and passing this information to a committee machine to assign appropriate confidence intervals (Specifications, p.12). While this may be an important point of distinction, this optimized decision making method is based on limitations in the specifications that are not present in the claims. Therefore, the applicant's arguments are not deemed to be persuasive and the instant claims are anticipated by Palsson.

II. Claims 34 through 45 are rejected under 35 USC § 102(e)(2) as being anticipated by Perlin (United States Patent #6,807,490; filed Feb. 15, 2000 ; issued Oct. 19, 2004). This rejection is maintained and reiterated from the previous office action, mailed Dec. 17, 2004.

Art Unit: 1631

Applicant argues that Perlin fails to perform any threshold test to analyze data before determining if an allele call should be made. After further review, the applicant's arguments are not deemed to be persuasive.

As stated in the previous office action, mailed Dec. 17, 2004, Perlin teaches a method for analyzing nucleic acid fragments that produces quantitative data, and fragment analysis on the data to characterize a DNA fragment to reduce sizing and quantitation errors. More specifically, a six step process is disclosed (Column 24, Line 38-56) in which Perlin teaches:

- (1) Finding the largest peak (area or height), and ensuring that is within a window on the allelic ladder;
- (2) Removing any peaks from the signal that either (a) have a DNA length that is not in a window of the allelic ladder, or (b) have a DNA amount that is not within some minimum percentage of the largest peak.
- (3) Calling the alleles by matching the DNA lengths of each sample peak to the DNA sizing windows on the allelic ladder;
- (4) Applying rules to check for possible data artifacts;
- (5) Computation of a quality score; and
- (6) Recording the designated alleles and the quality of the result

The applicant teaches an Envelop Caller algorithm that makes a call if "the signal's complexity is below a threshold (i.e. the signal is in the caller's operating region)" (specifications, p.13). According to this definition, Perlin applies "thresholding" to control for signal artifacts and make allele calls based on specific pre-determined parameters (Column 24, Line 38-56, Step 2 and 3). With respect to Claims 38-45, Perlin further discloses features of a system and software (computer readable medium) for the above described method (Columns 29 and 30, lines 59-67 and 1-36, respectively; and Column 32, lines 8-30).

Art Unit: 1631

In the independent claims 34, 38, and 42, the applicant discloses methods for: (1) receiving the signal representing nucleic acid information; (2) analyzing the signal to determine if the signal meets a threshold test of an allele caller making a correct call; (3) making a allele call for the signal if the threshold test is met. The applicant teaches three different algorithms for generating numerical quality scores used for determining if allele calls should be made, one of which uses thresholding. This is not specifically present in the claims. Furthermore, if one discloses a method of analyzing a signal to determine "if an allele caller has made a correct allele call", this implies that an allele call has been made. Therefore is logical to assume that an allele call has been made in Step 2 of Claims 34, 38, and 42, and that this has been done via a "threshold test" as the applicant has not disclosed any algorithms, quantitative methods, or decision-making methods other than a "threshold test." The applicant's argument that Perlin "fails to use thresholding as a test to determine if an allele call is made" is one based on limitations in the specification that are not present in the claims. Thus, Perlin anticipates the instantly claimed invention.

Applicant further argues that Perlin fails to teach the use of nucleic acid information for at least panel determination. After further review, the applicant's arguments are not deemed to be persuasive.

In Claim 35, the applicant discloses a method whereby nucleic acid information is used to determine nucleic acid length, panel determination, and energy level information, and wherein the nucleic acid length, panel determination, and energy level information are used for analyzing the signal. The applicant also discloses the computation of an energy level for each panel if at least three energy panels exist (Claim 36), and comparing the energy levels of the panels to

determine if a threshold test is met (Claim 37). As defined by the applicant, a panel is "a large section of the signal that is bounded by the signals deep local minima" (specifications, p.13). The applicant further discloses the process by which the original signal is divided into panels at each minimum (specifications, p.14). For example, if at least three panels exist the applicant discloses an algorithm that computes an energy level for each panel. To clarify previous concerns raised by the applicant regarding Figure 4 (Perlin; US Patent 6,807,490), we believe this to be a typo as Figure 6 (below) is more relevant in that the data has been divided into multiple panels (i.e. more than three).

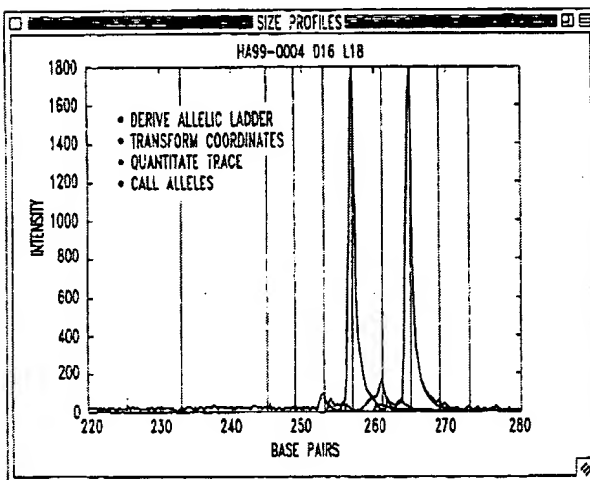


Fig. 6 (Perlin)

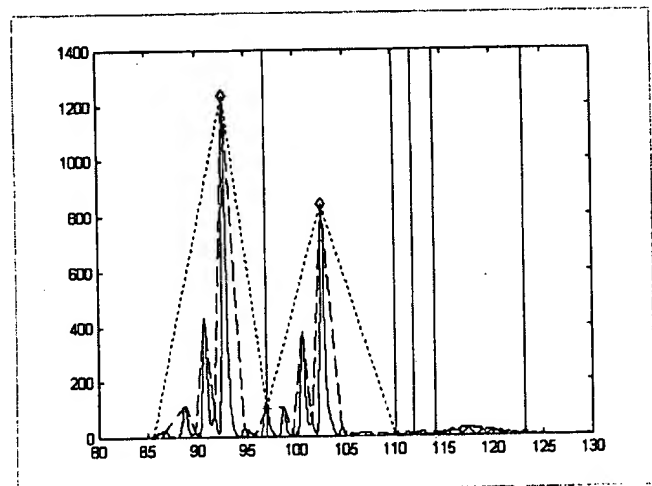


Fig. 7 (Applicant)

Perlin teaches a method of allele calling using quantitated corrected data (US Patent 6,807,490; Column 24, Line 38-56). Alleles are called by matching sample peaks relative to ladder peaks that serve as controls (Perlin, Column 23 Lines 42-53), where the term "ladder peaks" refers to standard calibrated DNA reference lengths used for comparison with observed data. Perlin is silent to the term "panel" but uses the term "DNA sizing windows on the allelic ladder." Window

Art Unit: 1631

widths are established using a mathematical "minimization" method. Panel determination is achieved by the computation of a quality score, particularly for those data apparently free of data artifacts (where maximum signal is present). Figures 6 displays the results of ladder processing, peak quantification, and allele calling, where the data has been divided into eight panels (previous page) via methods previously mentioned. This is a species of the instantly claimed invention, and thus Perlin anticipates the instantly claimed invention.

NEW MATTER

I. Claims 35-37, 39-41, and 43-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claims 35, 39, and 43 disclose a method, a system, and a computer-readable medium wherein "the nucleic acid information is used to determine the nucleic acid length, panel determination, and energy level information, and wherein the nucleic acid length, panel determination, and energy level information are used for analyzing the signal." (Note: Claims 35, 39, 43 were amended to include the underlined information, which is also present by dependency of claims dependent therefrom). The applicant separately teaches the use of nucleic acid information to determine nucleic acid length, panel determination, and energy computation information. The applicant also teaches the use of an Envelope Caller to "assess the complexity of a signal from the nucleic acid sequencer" (specifications, p.13). Although the applicant does not define what

is meant by "complexity of a signal", it is clear that energy level information is dependent upon both panel determination and nucleic acid information for determination. However, as disclosed in the specifications (p.15), the Envelope Caller algorithm analyzes the signal by performing a threshold test on the three largest energy levels, and not "nucleic acid length, panel determination, and energy level information" (collectively). This limitation is not taught in the specification and is not present within the scope of the original claims, thus Claims 35-37, 39-41, and 43-45 are rejected as they introduce NEW MATTER. This rejection is necessitated by amendment.

Provisional Obviousness-Type Double Patenting Rejection

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321 (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

Claims 34, 38, and 42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 14, and 25 of co-pending Application No. 09/911,903. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the broadly encompassing scope of the instantly claimed invention making the inventions to have overlapping embodiments. For example, the aforementioned claims in the pending applications (claim 34 in the instant application versus claim 3 in Application No. 09/911,903) have the similar steps of: 1) receiving a signal representing nucleic acid information; 2) [using a computer], analyzing the signal to determine if the signal meets a threshold test of an allele caller making a correct call; and 3) making an allele call for the signal if the threshold test is met. Claims 34, 38, and 42 of the instant application are directed to a computer-implemented method, computer readable medium, and system for "processing a signal" (preamble) with the final step of "making a correct allele call," whereas claims 3, 14, and 25 of co-pending Application No. 09/911,903 are directed to a computer-implemented method, computer readable medium, and system for "making allele calls" (preamble) with the final step of making an allele call. Thus, because of the similar steps (example provided for above) and the final result it would have been obvious that the "processing of a signal" as instantly claimed would overlap the embodiments of "making an allele call" (Application No. 09/911,903). This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Further, it should be noted this rejection has been set forth in view of Applicant's amendment to claims 3, 14, and 25 of co-pending Application No. 09/911,903 on 29 September 2004.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 8/5/05
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER